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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/341,590	07/12/1999	BJARNE DUE LARSEN	50412/008001	5316
21559	7590	01/08/2008	EXAMINER	
CLARK & ELBING LLP 101 FEDERAL STREET BOSTON, MA 02110			LUKTON, DAVID	
			ART UNIT	PAPER NUMBER
			1654	
			NOTIFICATION DATE	DELIVERY MODE
			01/08/2008	ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

patentadministrator@clarkelbing.com

<b>Office Action Summary</b>	<b>Application No.</b>		<b>Applicant(s)</b>	
	09/341,590		LARSEN, BJARNE DUE	
	<b>Examiner</b>		<b>Art Unit</b>	
	David Lukton		1654	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 10/3/07.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 83, 87, 88 and 114-149 is/are pending in the application.
- 4a) Of the above claim(s) 114-149 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 83 is/are rejected.
- 7) ☒ Claim(s) 87 and 88 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
     Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
     Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)            | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

Pursuant to the directives of the response filed 10/3/07, claim 83 has been amended, and claims 114-149 added. Claims 83, 87, 88, 114-149 are now pending. Claims 114-149 are withdrawn from consideration, as they do not encompass the elected peptide (Leu-enkephalin-(Lys)<sub>6</sub>; elected on 8/24/00). Claims 83, 87, 88 are examined in this Office action.

Applicants' arguments filed 10/3/07 have been considered and found persuasive in part.



Claim 83 is objected to. On page 5, line 5 of the response (filed 10/3/07) "melanotan" is recited. The peptide corresponding to this begins with the following:

Ac-N1le4-Asp5-His6

The principle issue here is that "1le" should instead be - - Ile - - ; i.e., the "1" should be an uppercase "I". Second, the numbers should instead be superscripts, i.e., as follows: *Ac-N-Ile<sup>4</sup>-Asp<sup>5</sup>-His<sup>6</sup>*-



The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this action.

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claim 83 is rejected under 35 U.S.C. §102(b) as being anticipated by Brent (USP 5512473).

Brent discloses SEQ ID NO: 4, which begins with the following:

Met-Ser-Gln-Glu-Arg-Pro-Thr-Phe-Tyr-Arg-Gln-Glu-Leu-Asn-Lys-Thr-Ile-  
Trp-Glu-Val-Pro-Glu-Arg-Tyr-Gln-Asn-Leu-Ser-Pro-Val-Gly-Ser-Gly-Ala-  
Tyr-Gly-Ser-Val-Cys-Ala-Ala-Phe-Asp-Thr-Lys-Thr-Gly-Leu-Arg-Val-Ala-  
Val-Lys-Lys-Leu-Ser-Arg-Pro-Phe-Gln-Ser-Ile-Ile-His-Ala-Lys-Arg-Thr-Tyr-  
Arg-Glu-Leu-Arg-Leu-Leu-Lys-**His-Met-Lys-His-Glu-Asn**-Val-Ile-Gly-Leu-  
Leu-Asp-Val-Phe-Thr-Pro-Ala-Arg-Ser-Leu...

As is evident, this contains the following subsequence:

His-Met-Lys-His-Glu-Asn

This corresponds to "Z" being His-Met-NH<sub>2</sub>, and "X" being (Lys)<sub>p</sub>(Xaa)<sub>q</sub>

Thus, the claim is anticipated.



Claim 83 is rejected under 35 U.S.C. §102(e) as being anticipated by Kemp (USP 5688760).

Kemp discloses a peptide in figure 1. Beginning at residue 102, the following subsequence is present: ...KKKRRTRSAW...

This anticipates claim 83 for the case of "X" being the pentapeptide **TRSAW**, and "Z" being **KKKRR**.



Claim 83 is rejected under 35 U.S.C. §102(e) as being anticipated by Tsien (USP 5625048)

Tsien discloses SEQ ID NO: 1.

Beginning at residue #77, the following subsequence is present:

...H-M-K-Q-H-A...

This corresponds to "Z" being His-Met-NH<sub>2</sub>, and "X" being (Lys)<sub>p</sub>(Xaa)<sub>q</sub>



Claim 83 is rejected under 35 U.S.C. §102(e) as being anticipated by Melief (USP 5679641).

Melief teaches SEQ ID NO: 14, which is the following:

KQSQHMTEV

This corresponds to "Z" being His-Met-NH<sub>2</sub>, and "X" being (Lys)<sub>p</sub>(Xaa)<sub>q</sub>



Claim 83 is rejected under 35 U.S.C. §102(e) as being anticipated by Harris (USP 5985829).

Harris teaches SEQ ID NO: 1. Beginning at residue number 164, the following subsequence is present:

...K-Q-S-Q-H-M-T...

This corresponds to "Z" being His-Met-NH<sub>2</sub>, and "X" being (Lys)<sub>p</sub>(Xaa)<sub>q</sub>

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a). The practice of automatically extending the shortened statutory period an additional month upon filing of a timely first response to a final rejection has been discontinued by the Office. See 1021 TMOG 35.

A SHORTENED STATUTORY PERIOD FOR RESPONSE TO THIS FINAL ACTION IS SET TO EXPIRE THREE MONTHS FROM THE DATE OF THIS ACTION. IN THE EVENT A FIRST RESPONSE IS FILED WITHIN TWO MONTHS OF THE MAILING DATE OF THIS FINAL ACTION AND THE ADVISORY ACTION IS NOT MAILED UNTIL AFTER THE END OF THE THREE MONTH SHORTENED STATUTORY PERIOD, THEN THE SHORTENED STATUTORY PERIOD WILL EXPIRE ON THE DATE THE ADVISORY ACTION IS MAILED AND ANY EXTENSION FEE PURSUANT TO 37 CFR 1.136(a) WILL BE CALCULATED FROM THE MAILING DATE OF THE ADVISORY ACTION. IN NO EVENT WILL THE STATUTORY PERIOD FOR RESPONSE EXPIRE LATER THAN SIX MONTHS FROM THE DATE OF THIS FINAL ACTION.



Any inquiry concerning this communication or earlier communications from the examiner should be directed to David Lukton whose telephone number is 571-272-0952. The examiner can normally be reached Monday-Friday from 9:30 to 6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang, can be reached at (571)272-0562. The fax number for the organization where this application or proceeding is assigned is 571-273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 571-272-1600.

A handwritten signature in black ink, appearing to read 'David Lukton', written in a cursive style.

DAVID LUKTON, PH.D.  
PRIMARY EXAMINER